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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,469	11/12/2003	Fred W. Chapman	009.4039	9404

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EXAMINER	
PATEL, NATASHA	
ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/712,469	Applicant(s) CHAPMAN ET AL.	
	Examiner Natasha N. Patel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *23-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12 November 2003*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-22, drawn to a method of controlling an external defibrillator, classified in class 607, subclass 7.

   II. Claims 23-44, drawn to an external defibrillator, classified in class 607, subclass 5.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus. For example, the physical parameter can be obtained by some mechanism other than a plurality of electrodes such as a pressure sensor or an oxygen sensor.

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mary Redman on 4/19/06 a provisional election was made with traverse to prosecute the invention of the method of controlling an external defibrillator, claims 1-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-44 withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

8. Claims 1-3, 8-11, 14-16, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US Patent 6,553,257) in view of Walcott et al. (US Patent 6,556,865).

9. Regarding Claim 1, Snyder discloses a method of controlling an external defibrillator configured to supply a defibrillation shock to a patient, comprising the steps of obtaining and analyzing a physical parameter (ECG) from a patient to determine whether the patient should be treated with a defibrillation shock (see col. 6, lines 56-58); indicating that CPR therapy should be administered for a predetermined CPR therapy period, and charging an energy storage device for at least a portion of the

predetermined CPR therapy period (see col. 2, lines 49-50); and discharging the energy storage device to thereby supply the defibrillation shock to the patient, after the predetermined CPR therapy period (see col. 2, lines 54-56). The examiner considers that the CPR therapy period is predetermined because instructions for the operation of the device are stored in ROM of controller 12 (see col. 6, lines 32-36).

Snyder does not disclose monitoring while CPR therapy is not being administered. Walcott discloses monitoring while CPR is not being administered (see col. 11, lines 28-35). The examiner considers that if ECG analysis is carried out to determine what type of therapy to provide, then the therapy is the result of the analysis and therefore, cannot occur at the same time as the analysis. Snyder teaches that the occurrence of chest compressions during monitoring results in disturbances (artifacts) in the ECG signal, which may be mistaken for shockable signals (see col. 3, lines 46-54) and lead to the defibrillation of the heart at inappropriate times. Thus, one of ordinary skill in the art at the time of the invention would have found it obvious to obtain and analyze the ECG while CPR is not being administered in order to reduce signal noise and provide appropriate therapy without the hassle of additional signal processing circuitry.

10. Regarding Claims 2 and 15, Snyder discloses obtaining and analyzing a signal representing a physical parameter (see col. 2, lines 31-37) to determine appropriate treatment. Snyder does not disclose a viability index. Walcott discloses obtaining a viability index from the physical parameter (see col. 12, lines 21-26) and comparing the viability index to a predetermined threshold (see col. 12, lines 58-64) to identify whether a heart condition treatable initially with a defibrillation shock is indicated or whether a

heart condition treatable initially with CPR therapy is indicated (see col. 11, lines 28-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a viability index in order to determine appropriate treatment because the viability index accurately quantifies the condition of the heart using physical parameters, such as ECG signals, that are easy to obtain (see col. 11, lines 7-12).

11. Regarding Claims 3 and 16, Walcott further discloses comparing the viability index to a predetermined CPR therapy threshold (see col. 13, lines 13-16) to determine a recommended CPR therapy period (see col. 13, lines 16-21). The examiner considers that since the duration of ventricular fibrillation depends on the duration of CPR therapy (see col. 12, lines 11-20), the viability index is essentially determining a recommended CPR therapy period. Once again, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the viability index to determine how long to perform CPR because the viability index quantifies the condition of the heart (see col. 13, lines 13-16) and can therefore indicate how much CPR is necessary to get the heart back to normal conditions.

12. Regarding Claim 8, Snyder discloses charging the energy storage device to a charge magnitude and maintaining the charge magnitude, for the predetermined CPR therapy period (see col. 6, lines 5-9). The examiner considers that the charge is maintained for the 10 extra seconds before the CPR period ends.

13. Regarding Claims 9, 10, 21, and 22, Snyder discloses visually and audibly indicating that CPR therapy should be administered for a predetermined CPR therapy period (see col. 5, lines 1-23 and 30-45). By indicating when to administer a

compression and when to stop, the indicators are indicating a CPR therapy period. Furthermore, since the processor is responsible for timing the indications (see col. 5, lines 41-45) and the instructions for the processor are predetermined and stored in the ROM (see col. 6, lines 34-41), the CPR therapy period is predetermined.

14. Regarding Claim 11, Snyder discloses discharging the energy storage device less than ten seconds after the predetermined CPR therapy period (see 5-10 seconds; col. 5, lines 15-24).

15. Regarding the steps of obtaining/analyzing and discharging in Claim 14, see the rejection of similarly worded claim 1 above. Regarding the step of indicating, Snyder additionally discloses maintaining the charge magnitude for at least a portion of the predetermined CPR therapy period (see col. 6, lines 5-9). The examiner considers that the charge is maintained for the 10 extra seconds before the CPR period ends. Furthermore, regarding the step of charging, Snyder discloses charging an energy storage device to a charge magnitude, if the patient should be treated with a defibrillation shock (see col. 5, line 65- col. 6, line 4). The examiner considers that the energy storage device (see col. 6, line 66- col. 7, line 5) has to have some charge magnitude in its charged state because if there were no magnitude, the energy storage device would be uncharged and incapable of delivering a defibrillating shock.

16. Claims 4, 5, 12, 13, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US Patent 6,553,257) and Walcott et al. (US Patent 6,556,865) in view of Snyder et al. (US Patent 6,356,785).

17. Regarding Claims 4, 5, 12, 13, 17 and 18, Snyder discloses a CPR therapy period lasting between the times indicated by the operator (see col. 4, lines 41-47). Snyder does not explicitly disclose that this CPR therapy period is a duration of time. However, any period with a start and a stop inherently includes a duration of time. Furthermore, if CPR is being performed, there will inevitably be a certain number of chest compressions delivered during the therapy period. It is common and well known to define a CPR therapy period with a duration of time or a number of chest compressions as shown by Snyder ('785; col. 9, lines 41-55). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to define the CPR therapy period by a duration of time or a number of chest compressions because they are both easily quantifiable and nationally used by the American Heart Association.

18. Claims 6, 7, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. (US Patent 6,553,257) and Walcott et al. (US Patent 6,556,865) in view of Couche et al. (US Patent 5,222,480).

19. Regarding Claims 7 and 20, Snyder discloses that the predetermined charge rate is a value such that the energy storage device is charged to the charge magnitude in a time that is substantially equivalent to the predetermined CPR therapy period (see col. 6, lines 1-9). Although the CPR therapy period ceases within ten seconds after the energy storage device has reached its charge magnitude, the examiner considers the ten seconds still makes the two time intervals substantially equivalent. The examiner also considers that the start time for CPR therapy would coincide with the time at which

the energy storage device starts charging since CPR therapy would not have started until after the monitoring step for the reasons given above in the rejection of Claim 1.

20. Regarding Claims 6 and 19, Snyder discloses charging the energy storage device to a charge magnitude (see col. 5, line 65- col. 6, line 4). The examiner considers that the energy storage device (see col. 6, line 66- col. 7, line 5) has to have some charge magnitude in its charged state because if there were no magnitude, the energy storage device would be uncharged and incapable of delivering a defibrillating shock. Snyder does not elaborate on the charge rate. Couche discloses charging the energy storage device to a charge magnitude at a predetermined charge rate (see col. 5, lines 65-66). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to implement a predetermined charge rate that allowed for enough energy to be stored by the time CPR therapy ended so that the discharge could effectively defibrillate the heart of the patient. For example, if the charge rate were not high enough, the amount of energy in the energy storage device might not be enough to successfully shock the heart (see col. 2, line 34-37). Also, if the charge rate were too high, the energy storage device would have to maintain the charge for a longer amount of time until the CPR therapy ended, resulting in charge decay (see col. 6, line 15).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NNP
4/26/06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766